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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/509,934 05/03/00 STEINMEYER

A SCH1747

EXAMINER

HM12/0912

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ART UNIT

PAPER NUMBER

1616

DATE MAILED:

09/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/509,934

Applicant(s)

Steinmeyer et al.

Examiner

Sabiha Qazi

Group Art Unit
1616



☒ Responsive to communication(s) filed on May 3, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-13 is/are pending in the application.

Of the above, claim(s) 12 and 13 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 12 and 13 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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First Office Action on Merits

Status of the Application

Claims 1-13 are pending.

Claims 1-11 are rejected.

Claims 12 and 13 are withdrawn from consideration as non elected invention.

Election/Restriction

This application contains claims 1-13 are directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art.

- I. Claims 1-11, drawn to compounds and method for preparing the compounds, classified in class 552, subclass 540+.
- II. Claims 12 and 13, drawn to intermediate compounds, classified in class 549, subclass 1+.

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The inventions are distinct, each from the other because of the following reasons:

The invention of group I and group II are drawn to structurally dissimilar compounds with different cores which are structurally dissimilar. Compounds of group I are drawn to vitamin D compounds, their preparation and method of use whereas compounds of group II are epoxy dioxalane compounds. These groups are separate inventions and are patentably distinct. A reference used to reject invention of group I will not be used to reject the invention of group II.

Accordingly, unity of invention is lacking and restriction of the invention in accordance with the rules of unity of invention is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for Group I is not required for Group II, the database and other searches for the entire genus would represent excessive burden on the Examiner. The restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Anthony Zellano on 9/5/00 a provisional election was made with traverse

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to prosecute the invention of group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12 and 13 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Affirmation of this election must be made by applicant in replying to this Office action. Claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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It is suggested that in order to advance prosecution, the non elected subject matter be canceled when responding to this office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7-11 are rejected under 35 U.S.C. 101 because claimed invention is directed to nonstatutory subject matter. Claim 7-11 are drafted in terms of "use", however "use" is not one of the statutory classes of invention. Clinical Products v. Brenner, 1449 USPO 475, 476 (1966).

It is suggested that "The use of the" may be changed to "The method of use" in order to overcome this rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

2. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kersh et al. (WO 97/00242). See compound 106a and 106b on page 92 and example XXXIV on page 36 which has cyclopropyl group at C-25 position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Kirsh et al. (WO 97/00242). See the entire document especially formula I on page 1, example XXXIV on page 36. Kirsh et al teaches 25-substituted vitamin D derivatives, their process of making and method of use.

Instant claims differ from the reference in claiming a limited genus than the prior art. A cyclopropyl ring is the only substituent at 25 position whereas prior art teaches 3-7 membered carbocyclic or heterocyclic ring and other groups at the same position.

It would have been obvious to one skilled in the art at the time of the invention to prepare additional beneficial compounds and their compositions for medicinal use by selecting cyclopropyl ring at 25-position. This would have been obvious because 3-7 carbon cyclic rings at the same position has been taught by the prior art. Instant invention is the selection of prior art

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teachings. There has been ample motivation provided by the prior art to prepare the instant invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

The data showing any unexpected results would overcome the above 35 U.S.C. 103(a) rejection.

Minor Informalities

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The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Amended method claims must be supported by the specification.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi Ph.D.

9/8/00

Examiner, 1616